



Surgical treatment of rectal cancer in Poland — a report from a prospective, multi-centre observational study PSSO_01 conducted under the auspices of the Polish Society of Surgical Oncology

Tomasz Błaszkowski¹, Grzegorz Celban², Maciej Domagała³, Jarosław Janas⁴, Michał Jankowski⁵, Józef Kładny¹, Wiesław Janusz Kruszewski⁶, Konrad Listwan⁷, Zbigniew Lorenc³, Anna Madej-Mierzwa⁶, Adam Majewski⁴, Marek Mądrecki⁸, Jerzy Mielko⁹, Sebastian Mosiej¹⁰, Piotr Nowaczyk⁷, Mariusz Obrębski⁸, Tomasz Olesiński¹¹, Piotr Papaj¹², Oskar Pelzer¹³, Paweł Pius², Wojciech Polkowski⁹, Karol Rawicz-Pruszyński⁹, Andrzej Rutkowski^{11*}, Karol Tkaczyński⁵, Dorian Wiśniewski⁵, Wojciech Woźny¹³, Józef Wróbel¹², Wojciech M. Wysocki¹⁰, Wojciech Zegarski⁵

Introduction. Since 2016, as part of the PSSO_01 multi-centre research project conducted under the auspices of the Polish Society of Surgical Oncology, clinical data on rectal cancer treatment have been collected. The objective of the study was to illustrate the state of early results of surgical treatment.

Material and methods. The research project is multi-centre in nature. Data shall be collected electronically. The study protocol does not impose or suggest any course of procedure. It only systematizes the way data are collected for scientific purposes. The analysis of early results of surgical treatment was compared with the results of population studies from other European countries (Netherlands, Belgium).

Results. By the end of June 2018, 736 patients were registered in the study. In 399 (54.2%) an anterior resection was performed. More than half of patients undergoing subsequent surgical treatment (54.2%) receive neoadjuvant treatment, with the percentage of patients undergoing radiotherapy or radiochemical treatment for lower rectal cancer being about 70%. Most patients (96%) are operated in elective procedure. The percentage of laparoscopic surgeries is

The team of the researchers participating in the PSSO_01 project is listed in alphabetical order.

¹Department of General and Oncological Surgery, Pomeranian Medical University, Szczecin, Poland

²Department of Surgical Oncology, Jurassic Center of Oncology, Częstochowa, Poland

³Clinical Department of General, Colorectal and Trauma Surgery, Silesian Medical University, Sosnowiec, Poland

⁴Specialist Hospital of Dr. Alfred Sokołowski, Wałbrzych, Poland

⁵Department of Surgical Oncology, Oncology Center — Prof. Franciszek Łukaszczyk Memorial Hospital, Bydgoszcz, Poland

⁶Oncological Surgery Department, Gdynia Centre of Oncology, Polish Red Cross Memorial Maritime Hospital, Pomeranian Hospitals Ltd., Gdynia, Poland

Department of Oncological and General Surgery, Greater Poland Oncology Center, Poznań, Poland

⁸First Department of General and Oncological Surgery, Voivodeship Integrated Hospital in Płock, Poland

⁹Department of Surgical Oncology, Medical University of Lublin, Poland

 $^{^{10}} Department \ of \ Oncological \ Surgery, \ Maria \ Skłodowska-Curie \ Institute --Oncology \ Center, \ Kraków \ Branch, \ Poland$

¹¹Department of Oncological Gastroenterology, Maria Skłodowska-Curie Institute — Oncology Center, Warszawa, Poland

¹²Beskid Oncology Center — John Paul II Municipal Hospital, Bielsko-Biała, Poland

 $^{^{13}}$ First Department of General and Oncological Surgery, Voivodship Hospital Centre of the Jelenia Góra Basin, Jelenia Góra, Poland

^{*} principal author of the report

low (8.6%). Postoperative complications are observed in 21.1% of patients. Severe complications (grades III–V according to Clavien-Dindo classification) occur in 7.6% of patients undergoing surgery. Postoperative mortality is 1.1%. **Discussion.** Although the project does not have the character of a registry and does not allow for drawing wider conclusions concerning the compliance with the standards of qualification for neoadjuvant treatment, the important information is that more than half of rectal cancer patients receive preoperative treatment, and the percentage of severe postoperative complications does not exceed 10%.

Conclusions. The results of the PSSO_01 project are representative and reflect the actual situation concerning surgical treatment of rectal cancer patients in Poland.

NOWOTWORY J Oncol 2018; 68, 3: 119-126

Key words: rectal cancer, PSSO, surgical treatment

Introduction

According to the National Cancer Registry (Krajowy Rejestr Nowotworów — KRN), 5816 cases of rectal cancer were reported in 2015 [1]. It is difficult to estimate the percentage of patients with newly diagnosed rectal cancer who underwent surgery, how many of these surgeries were of a radical nature, the percentage of combination treatment, in what percentage of operated cases sphincter-saving procedures were possible and restoration of gastrointestinal continuity, and how many patients underwent laparoscopic surgery? These are just some of the questions about the surgical treatment of rectal cancer patients that we do not have answers to. We can only rely on data from individual centers, usually specialist ones. In 2016, under the auspices of the Polish Society of Surgical Oncology (PSSO), a multi-centre observational study PSSO_01 project was launched, the main objective of which is clinical verification of the proposed risk of anastomotic leak after anterior resection. The study collects data on all rectal cancer patients operated in the participating centers. We obtain information on the pretreatment stage of cancer, type of surgery, percentage of laparoscopic surgeries, complications in the perioperative period, share of combination treatment (radiotherapy/radiochemiotherapy). In the case of anterior resection, we archive data on the occurrence of anastomotic leaks, the creation of a protective stoma and the restoration of the gastrointestinal tract continuity (closure of a protective stomata). The study is open and the size of the target group (patients undergoing anterior resection) was estimated at 846 cases. Although the study does not have the character of a register, the data collected so far make it possible to illustrate early results of surgical treatment of rectal cancer not only from the perspective of a single centre, but also on a national scale.

Methodology and material

The research project was approved by the Bioethics Commission operating at the Maria Skłodowska-Curie Institute — Oncology Center in Warsaw. The study is observational and non-interventional, which means that all patients

are treated according to the applicable standards and at no stage of the study there is a need to perform any additional medical procedures other than those which, according to the doctor's knowledge and experience, constitute the optimal way of management for the patient. Research data are collected electronically using an encrypted application owned by PSSO. All data collected centrally are anonymous. Sensitive data such as PESEL number, gender, date of birth, initials of the patient's given name and surname are not collected centrally, so identification of the patient is only possible at the research centre. The study protocol does not impose or suggest any course of procedure. It only systematizes the way data are collected for scientific purposes. The PSSO_01 project is open to centers that meet the following criteria:

- the number of patients with primary rectal cancer diagnosis, surgically treated within 12 months ≥ 20
- the number of anterior resections performed within
 1 year in patients with rectal cancer ≥ 10
- possibility to monitor the appearance of postoperative complications within a minimum of 30 days after surgery and distant results of surgical treatment within 12 months after surgery.

Centers in which a protective stoma is routinely (in each case) performed as an integral part of a surgery defined as "low anterior resection" cannot be included in the study, except where resections with anastomosis at a distance ≤ 3 cm from the anal verge are considered as low anterior resections. Recruitment of centers is open and including other centers is possible at any time during the project. Currently, 21 centers are registered, out of which 14 are active (Fig. 1). The target group are patients who meet the following criteria:

- primary rectal adenocarcinoma (lower limit of the tumor at a distance of up to 15 cm from the anal verge),
- anterior resection of the rectum,
- surgery according to total mesorectal excision (TME) standards or partial mesorectal excision in case of high tumor position.

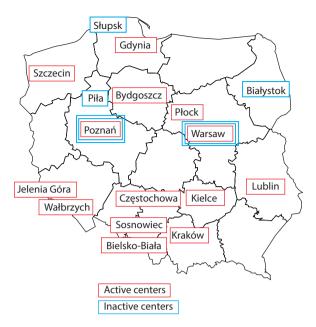


Figure 1. Centers participating in the PSSO_01 project (June 2018)

The study protocol requires that all patients with primary rectal adenocarcinoma diagnosed, who come to the centre for surgical treatment — regardless of the type of operation — must be reported. This is necessary to demonstrate that the material of patients qualified for detailed analysis of the target group was not subject to selection (the condition of publication in the indexed medical literature according to STROBE Statement criteria). Data collected in the study centre are reported electronically, after the registration of the centre and gaining access to the research application. It was assumed that the time needed to gather an appropriate group of patients to achieve the objectives of the study would be from 36 to 48 months (depending on the number of centers participating in the study). The protocol allows for the possibility of including additional centers during the implementation of the research project. The course of the study is supervised by the Coordinating Committee appointed by the Board of PSSO.

By the end of June 2018, 736 patients were registered in the study (471 men and 265 women). In 399 (54.2%) anterior resection was performed (Fig. 2). In 433 (58.8%) cases comorbidities were reported, which may increase the risk of complications in surgical treatment (diabetes, hypertension, ischemic heart disease) and/or positive history of abdominal surgery. Moreover, as early as at the time of diagnosis of cancer, distant metastases occurred in 87 (11.8%) patients qualified for surgical treatment. The current rate of recruitment allows us to assume that the size of the target group will be reached within the expected period of time.

Results of the analysis

Preoperative treatment

Neoadiuvant treatment is received by more than half of patients undergoing subsequent surgical treatment (54.2%). In the analyzed sample of 736 patients, high fractional dose radiotherapy (5 \times 5 Gy) was used in 238 (32.3%) cases, while in 43 (5.8%) patients it was combined with chemotherapy. Classical "long" radiochemical treatment was received by 104 (14.1%) patients. In 13 cases the only preoperative treatment was chemotherapy, in half of them the presence of distant metastases was observed as early as at the moment of diagnosis. In 44 patients the only preoperative treatment was radiotherapy with a total dose of 50.4 Gy in the form of monotherapy (without chemotherapy). It should be noted that the study protocol allows the inclusion of patients with upper rectal cancer in whom no preoperative treatment is used. Therefore, data relating to preoperative treatment require a detailed analysis, which is done in the chapter on surgical treatment.

Surgical treatment

A vast majority of registered patients are operated in elective procedure. Collected data indicate that only 4% of patients required emergency surgery. The percentage of laparoscopic surgeries is also low: 8.6%. Radical oncological surgery (according to the surgeon) was performed in 624 (84.8%) patients. The type of conducted surgeries has been shown in Figure 3. The most common types of rectal cancer resection surgeries are analyzed below.

Anterior resection

In 198 (49.6%) patients radiotherapy or radiochemiotherapy was applied before the surgery. In the case of anterior resection with low anastomosis, the preoperative treatment was received by 72.3% of patients.

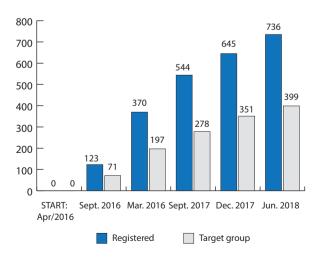


Figure 2. Recruitment in the PSSO_01 study

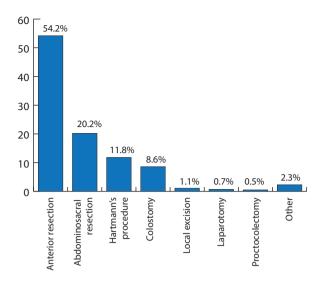


Figure 3. Type of performed surgeries

Laparoscopic surgery was performed in 36 (9.0%) patients (reports from 8 out of 14 active centers). In 95% of cases the anastomosis was performed using the stapling technique. Most of the anastomoses were performed with the end-to-end method (94.5%). End-to-side anastomosis is performed much less frequently (4.3%), while anastomosis with the J-pouch bowel reservoir is performed sporadically (only 2 such cases from one research centre have been reported). The distances between the anal verge and the anastomosis are presented in Table I. If a low anterior resection is defined as a surgery with an anastomosis up to 5 cm from the anal verge, the percentage of such procedures reaches 19.2%. In 90 (22.6%) patients, anastomosis requires initiating the left colon bend, which is a value similar to the reported percentage of resections with low anastomosis. In 91 (22.8%) cases the surgeon secured the anastomosis with a stoma. Out of 87 patients operated until the end of December 2017, in whom the surgeon secured the anastomosis with a stoma more than 6 months after surgery, 30 (34.4%) still have a stoma, including 8 (9.2%) patients with a stoma longer than 12 months after surgery and it may be assumed that the stoma is already permanent.

Abdominosacral resection

The study protocol does not distinguish between abdominosacral and abdominoperineal resections, assuming that these are cylindrical amputations with an appropriate margin within the pelvic floor and the tissues located above. All such surgeries should be classified as elective (100% of reported cases). The majority of patients undergoing abdominosacral amputation receive preoperative treatment — 77.2%. The operation is usually performed with the intention of oncological radicality — 96.6%. The percentage of laparoscopic surgeries is low — 12.8%.

Hartmann's procedure

In the majority of patients operated in this way, preoperative radiotherapy or radiochemical therapy is used (62.1%). This type of resection is more frequent in patients with a history of abdominal surgery and/or comorbidities — 66.7% and with the presence of synchronous distant metastases — 20.7% (Table II). In 16.1% of cases resection is palliative. Hartmann's laparoscopic procedure is performed rarely (2 cases reported).

Operations related to the creation of an intestinal stoma

The total percentage of patients with an intestinal stoma as a result of the surgery is 46.9%. Of these, in 12.2% of cases it is by definition a temporary stoma. However, observations made within 6 months after surgery indicate that 47.2% of patients still have an intestinal stoma and one should suspect that it may be a permanent stoma. Considering only radical surgeries, the percentage of patients with a permanent intestinal stoma is 42%.

Postoperative complications

Postoperative complications were observed in 21.1% of patients. The grade and severity of reported complications were determined according to the Clavien-Dindo classification [2] — Table III. Postoperative mortality was 1.1%. Severe complications requiring surgical treatment or ICU-management (grades III and IV) occurred in 7.6% of patients undergoing surgery. The total percentage of complications depending on the type of operation is presented in Figure 4. The highest risk of complications is associated with anterior resection with low anastomosis (up to 5 cm from the anal verge) (29.1%). The risk of anastomosis leaks is 10.6% in such case. A creation of a protective stoma reduces the risk of symptomatic leak, but it is still a high percentage of 9.9%. This is one of the reasons why a protective (tem-

Table I. Distance between the anastomosis and the anal verge

Table 1. Distance between the anastomosis and the anal verge		
Distance range	Number of cases	%
≤ 3 cm	35	8.8
> 3–5 cm	106	26.8
> 5–10 cm	191	48.2
> 10 cm	64	16.2
No data available	3	-

Table II. Type of surgeries performed vs data from the patient history and the grade of cancer at the moment of diagnosis

	Positive medical history*	Synchronous metastases	Urgent surgery
Anterior resection	56.1%	7.5%	0.5%
Abdominosacral resection	63.1%	6.7%	0.0
Hartmann's procedure	66.7%	20.7%	8.0%
Colostomy	49.2%	41.3%	22.2%
Local excision	87.5%	12.5%	12.5%
Laparotomy	60%	20.0%	0.0
Proctocolectomy	50%	0.0	0.0

^{*} concerns comorbidities and/or surgical treatment within the abdominal cavity

Table III. Postoperative complications according to the Clavien-Dindo classification

Grade	Definition	Number of cases n (%)
I	Any deviation from the correct (uncomplicated) postoperative course, without the need for pharmacological, surgical, endoscopic treatment and without interventional radiology procedures	43 (5.8)
II	Complications requiring pharmacological treatment. In addition, this group includes all cases requiring treatment: – postoperative blood transfusion, – total parenteral nutrition (except where total parenteral nutrition is a routine procedure arising from the type of surgery performed)	45 (6.1)
III	Complications requiring surgical or endoscopic treatment or interventional radiology procedures – without general anaesthesia (IIIA) – under general anaesthesia (IIIB)	40 (5.4)
IV	All life-threatening postoperative complications requiring treatment in ICU conditions – single organ failure (IVA) – multiple organ failure (IVB)	16 (2.2)
V	Death	8 (1.1)
No data available	-	3 (–)

porary) stoma remains open and becomes a permanent stoma. A risk of severe (grades: III–V) complications after abdominosacral amputation is 7.4% and is lower than after Hartmann's procedure: 10.3%. Overall, radical surgeries carry a higher risk of postoperative complications than palliative surgeries (22.1% vs 16.1%), but the percentage of severe complications (grades: III–V) is similar to that observed after palliative surgery: 8.7% vs 9.4% It should be noted that in the group of palliative surgeries non-resectional procedures predominate. The percentages of severe postoperative complications after certain types of rectal cancer resections are presented in Table IV.

PSSO_01 against the background of European research

The PSSO_01 research project does not meet the requirements of the register of rectal cancer surgical treatment, however, to the best knowledge of the authors of this report it is the first study based on prospectively collected clinical material, which allows for presenting collective results of surgical treatment from both large and smaller centers in Poland. The data collected so far have been compared with the results of the Dutch Surgical Colorectal Audit [DSCA] [3]

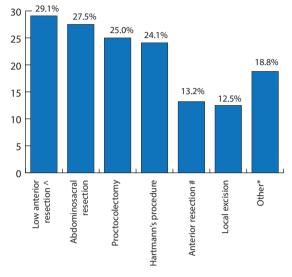
and the Belgian project PROCARE [4] — Table V. The Dutch Surgical Colorectal Audit was carried out in 2009-2011. In the following years, the audit covered 80%, 92% and 95% of patients treated surgically for colorectal cancer in the Netherlands. Rectal cancer is defined as tumors located up to 12 cm from the anal verge. The lesions located above were analyzed as colon cancer. An unquestionable success of the Dutch audit was the unification of standards of diagnostic and therapeutic management in Dutch hospitals, which resulted in the lack of differences between the results of oncological treatment of patients operated in both large and smaller centers [5]. Launched in 2006, the multi-centre PROCARE project focused on the results of treatment of patients with lower and middle rectal cancer (a cancerous tumor located 0-10 cm from the anal verge). The results obtained in PROCARE are of limited value, as only 37% of patients were included in the study.

Representativeness of the tested sample

Following the analysis made on the Dutch audit material, the PSSO_01 study identified large (over 50 rectal cancer/year operations), medium (20–50 patients/year) and small (up to 20 patients/year) centers [5]. In the analysis of the

Table IV. Type of resection surgery and risk of severe postoperative complications according to the Clavien-Dindo classification

Surgery type	Grade III	Grade IV	Grade V
Low anterior resection	8.5%	3.5%	-
Anterior resection	3.5%	1.6%	1.6%
Abdominosacral resection	5.4%	1.3%	0.7%
Hartmann's procedure	5.0%	3.4%	2.3%
Local excision	12.5%	-	-



- $^{\land}$ anterior resection with the anastomosis \leq 5 cm from the anal verge # anterior resection with the anastomosis > 5 cm from the anal verge
- # antenor resection with the anastomosis > 5 cm from the anal

Figure 4. Postoperative complications depending on the surgery type

PROCARE study, in order to determine the "volume" of the centre, the number of surgeries performed annually was also assumed, however, four groups were identified: < 30 surgeries/year; 30-50 / year; 50-100 / year and > 100 / year [4]. In the presented study for the purpose of comparative analysis, data from the last two groups of the PROCARE study have been combined. The results of PSSO_01 study are in this respect comparable to those presented by Dutch authors. They indicate that the vast majority of the reported patients are operated in medium-volume centers performing 20-50 surgeries a year. Different numerical criteria adopted in the PROCARE study would indicate that the majority of patients are subject to surgeries in large centers (76.7%). However, if we assumed that the average Belgian centers operate between 30 and 100 patients a year, then the percentage of patients treated in this defined group would be 48%.

In the PSSO_01 study material, it is worth noting that the number of men is twice as much as women. Comparing this with epidemiological data, which indicate a sustained trend in incidence in males and a plateau in incidence in females [1], the gender differences found in the analyzed group of patients seem to be representative for the general population and comparable with the data from other reports [4, 5]. In the PSSO_01 project we are waiting for the age of registered patients analysis. Due to the fact that all sensitive data (age, PESEL) are stored in the centre, such an analysis will be possible only after the completion of the study and obtaining raw data from each centre separately.

Although the recorded percentage of patients with synchronous distant metastases is comparable to those published in Dutch and Belgian reports, it seems to be underestimated in comparison to the Polish population as far as the experience of a Polish clinician involved in rectal cancer surgery is concerned. Firstly, we do not have population data on the severity of the disease at the time of diagnosis among newly registered cases in Poland, and secondly, some of these patients are not qualified for surgical treatment at all, or are operated on a palliative basis in other centers as a matter of urgency.

Nearly 60% of participants are patients with comorbidities and/or history of abdominal surgery and this value is significantly lower than in the Dutch report (95%). However, the reason for these differences may be that the PSSO_01 test protocol requires reporting only those cases where, in the opinion of the surgeon, comorbidities or surgical history are relevant to the planned surgery.

Neoadjuvant treatment

Short-term (5-day) irradiation monotherapy up to a total dose of 25 Gy and long-term radiation therapy up to a total dose of 50.4 Gy in combination with chemotherapy are standard preoperative treatments for rectal cancer patients, depending on the cancer stage and the assessment of tumor resectivity. The results of a Polish multi-centre randomized clinical trial comparing the efficacy of classical radiochemical treatment with short term radiotherapy combined with chemotherapy in the treatment of patients with primary non--resectional rectal cancer showed that the treatment results were similar [6]. The clinical application of these results is reflected in the increasing number of subgroups of patients treated preoperatively according to the following programme: short-term radiotherapy, chemotherapy and surgery. We found that 6% of patients (n = 44) received only long--term irradiation without chemotherapy. It is an acceptable method of treatment for patients with locally advanced

^{*} stoma, explorative laparotomy, other

Table V. PSSO_01 against the background of European studies

Feature	Poland PSSO_01	Belgium PROCARE [4, 8]	Netherland DSCA [3, 5]
Representativeness of the tested sample			
Participation of centers in recruitment:			
- small centers	7.9%	2.5% [4]	12.3% [5]
 medium-sized centers 	60.7%	20.8% [4]	63.4% [5]
– large centers	31.4%	76.7% [4]	24.2% [5]
Gender:			
– male	64%	61% [4]	62% [3]
– female	36%	39% [4]	38% [3]
Synchronous distant metastases	11.8%	9.2% [4]	8.6% [5]
Neoadjuvant treatment			
Preoperative treatment, total	54.2%	59.5% [4]	83.7% [3]
– radiotherapy	32.5%	5% [4]	55% [3]
– radiochemotherapy	20%	54.5% [4]	28.6% [3]
– others	1.8%	-	_
Surgical treatment			
Surgical access:			
– laparoscopy	8.6%	_	38.1% [3]
Urgent surgeries	4%	_	2.8% [3]
Surgery type:			
- abdominosacral resection	20.2%	20.4% [4]	30.5% [3]
– Hartmann's procedure	11.8%	1.4% [4]	19.2% [5]
– anterior resection	54.2%	71.6% # [4]	45.8% *[3]
 local excision 	1.1%	1.2% [4]	-
Protective stoma	22.8% ^	-	65.3% & [3]
Early results of surgical treatment			
Postoperative complications total:	21.1%	_	38.7% [3]
Anastomosis leak	6.5% ^	_	10.9% & [3]
Repeated surgery	_	_	16% [3]
Mortality (30 days after surgery)	1.1%	1.1% [8]	2.1% [3]

[#] Percentage of surgeries defined as "sphincter-saving surgeries"

cancer and with contraindications for systemic treatment. The total percentage of patients undergoing neoadjuvant treatment is similar to that reported in the PROCARE report (54.2% vs 59.5%) and significantly lower than in the study by Dutch authors (54.2% vs 83.7%) — Table V. The Dutch audit concerned patients with the diagnosis codified as C20 according to ICD10 classification, but it should be noted that in 77.9% of registered patients cancer was located within 10 cm from the anal verge [3]. This may explain the observed difference in the percentage of patients treated with neoadjuvant treatment between the PSSO_01 study report and the results of the Dutch audit. The analysis of a subgroup of patients with anterior resection with anastomosis up to 10 cm from the anal verge or abdominosacral resection (i.e. those in whom the tumor location might indicate the need for preoperative treatment) shows that the percentage of patients receiving neoadjuvant treatment is 69.2%.

Surgical treatment

Low percentage of laparoscopic surgeries in Poland is the most significant difference observed in comparative analysis — Table V. The Dutch audit completed in 2011 indicated that the percentage of laparoscopic surgeries reached 38.1%. A study conducted in 2015 in selected centers previously participating in the DSCA showed that the percentage of laparoscopic surgeries in small centers reaches 59.8%, in medium centers — 44.8%, and in large centers — 45.7%. The difference was statistically significant, indicating that the majority of laparoscopic surgeries are performed in small centers [5]. PSSO_01 project data indicate that in Poland the total percentage of such surgeries does not exceed 10%. The reasons for these differences cannot be found in the conducted surgeries mode, as the percentage of urgent procedures reported in the PSSO_01 project and DSCA results are similar: 4% vs 2.8%

The percentage of abdominosacral resections reported in PSSO_01 is almost identical to the PROCARE project results. On a global scale, this percentage may be significantly different, as both PSSO_01 and PROCARE covered only a part of the centers.

An interesting observation is the comparison of the percentage of resections with the Hartmann's procedure,

^{*} Percentage of surgeries defined as "surgeries with primary anastomosis"

[^] Percentage with reference to surgeries defined as "anterior resection"

 $^{\&}amp;\, Percentage\, with\, reference\, to\, surgeries\, defined\, as\, "surgeries\, with\, primary\, an astomosis"$

which in the Belgian study is significantly lower than in PSSO_01 and DSCA. PROCARE shows a high percentage of sphincter-saving surgeries: 71.6%. If resections with primary anastomosis (anterior resection) are defined by this term, the corresponding data from the DSCA and PSSO_01 projects are respectively: 45.8% vs 54.2% The only explanation for these differences seems to be the selection of centers and the incompleteness of the Belgian register [4].

Also noteworthy is the high percentage of protective stomata selected in the DSCA material: 65.3%. As early as at an early stage of this audit, a clear increase in the proportion of protective stomata identified compared to previous data collected during the TME trial (1996–1999) was observed: 70% vs 57% (p < 0.001). However, this fact did not have an impact on the reduction of the percentage of anastomosis leaks: 11.4% vs 12.1%; p = 0.640 [7]. Observations made then by Dutch authors were the basis for designing and defining the main objectives of the PSSO_01 study.

Early results of surgical treatment

The total percentage of complications at the level of 21% clearly differs from that observed in the Dutch report (38.7%). However, the advantage of the PSSO 01 project is the prospective registration of the category of complications according to the Clavien-Dindo classification (Table III). Belgian authors reported the percentage of severe complications separately for sphincter-saving surgery and after abdominosacral resection: 7.8% vs 5.4% respectively. The total postoperative mortality rate was 1.1% [8]. Assuming that we consider as serious complications those that fall under category III and IV, and the death is classified as category V, the relevant percentages recorded in the PSSO_01 project are equal: anterior resection — 7.5%; abdominosacral resection — 6.7%; total postoperative mortality rate — 1.1%. As we can see, these values are almost identical to those reported in the PROCARE study. Interesting insights also apply to registered cases of anastomosis leaks. In the PSSO_01 project, the total leakage rate after anterior resection is 6.5%. The DSCA register gives a value of 11%, but it should be remembered that it concerns anastomoses after rectal cancer resection located up to 12 cm from the anal verge. Analyzing a subgroup of patients from the PSSO_01 study in which the anastomosis was performed up to 10 cm from the anal verge, i.e. comparable to DSCA material, the percentage of symptomatic leaks is 8%. The higher leakage rate recorded in the Dutch report is probably due to the fact that the audit covered almost 100% of the centers.

Final remark

The PSSO initiative through the PSSO_01 project enables the presentation of early results of surgical treatment of rectal cancer in Poland from a broader perspective than before. The results of the analysis of the collected research material

within the PSSO_01 project so far seem to indicate that it is comparable to the material used to create reports presented by Dutch and Belgian researchers. This may indicate that it will be representative for the entire Polish population. Although the PSSO_01 project does not allow for drawing wider conclusions concerning the compliance with the standards of qualification for neoadiuvant treatment, the important information is that more than half of rectal cancer patients receive preoperative treatment, and the percentage of severe postoperative complications does not exceed 70%. This value is similar to that given in reports from other European countries. Observations relating to the methods of surgical treatment that emerge from comparative analysis allow us to illustrate the difference in the percentage of laparoscopic surgeries performed in Poland in comparison with other European countries. At the same time it should be noted that the percentages of particular surgery types do not differ significantly from those reported in the DSCA. Comparison with the PROCARE study reveals significant difficulties in the interpretation of results, mainly due to significant differences in the reported percentage of Hartmann's procedures. Early surgical treatment results recorded in PSSO_01 are similar to those presented in the PROCARE and DSCA studies.

The functionality of the PSSO application used to collect clinical data on surgical treatment of rectal cancer allows for its development and creation of further research projects focusing on the treatment of patients with this cancer. An example can be the PSSO_02 test module added to the application and launched in July 2018. The application can therefore be regarded as the basic platform for data collection with the possibility of attaching modules related to a specific research project (PSSO_01, PSSO_02). The PSSO_01 Research Coordination Committee and the Board of the Polish Society of Surgical Oncology invite other centers that would be interested in participating in current research projects, as well as to design new research that would be in line with the issues related to the treatment of rectal cancer.

Conflict of interest: none declared

Andrzej Rutkowski, MD, PhD

Maria Skłodowska-Curie Institute — Oncology Center Department of Oncological Gastroenterology ul. Roentgena 5, 02–781 Warszawa, Poland e-mail: arutkowski@coi.waw.pl

Received: 21 Sept 2018 Accepted: 25 Sept 2018

References

- Didkowska J, Wojciechowska U, Olasek P. Nowotwory złośliwe w Polsce w 2015 roku. Warszawa: Centrum Onkologii — Instytut, Krajowy Rejestr Nowotworów, 2017.
- Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and result of a survey. *Ann Surg* 2004; 240: 205–213.

- Van Leersum NJ, Snijders HS, Henneman D et al. The Dutch surgical colorectal audit. Eur J Surg Oncol 2013; 39: 1063–1070.
- Jegou D, Penninckx F, Vandendael T et al.; PROCARE. Completeness and registration bias in PROCARE, a Belgian multidisciplinary project on cancer of the rectum with participation on a voluntary basis. Eur J Cancer 2015; 51: 1099–1108.
- Jonker FHW, Hagemans JAW, Burger JWA et al.; Dutch Snapshot Research Group. The influence of hospital volume on long-term oncological outcome after rectal cancer surgery. Int J Colorectal Dis 2017; 32: 1741–1747.
- Bujko K, Wyrwicz L, Rutkowski A et al.; Polish Colorectal Study Group. Long-course oxaliplatin-based preoperative chemoradiation versus 5 × 5 Gy and consolidation chemotherapy for cT4 or fixed cT3 rectal cancer: results of a randomized phase III study. Ann Oncol 2016; 27: 834–842.
- Snijders HS, van den Broek CB, Wouters MW et al. An increasing use of defunctioning stomas after low anterior resection for rectal cancer. Is this the way to go? Eur J Surg Oncol 2013; 39: 715–720.
- Leonard D, Penninckx F, Kartheuser A et al.; PROCARE. Effect of hospital volume on quality of care and outcome after rectal cancer surgery. Br J Surg 2014; 101: 1475–1482.